STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	450044	A. BUILDING _____ B. WING _____	C 01/04/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UT SOUTHWESTERN UNIVERSITY HOSPITAL	6201 HARRYHINES BLVD DALLAS, TX 75390

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation (s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. An unannounced, complaint survey was conducted on site. An entrance conference was held with the hospital delegated representatives on the morning of 12/27/19. The hospital representatives were informed that the survey would be conducted according to the survey protocol in the State Operations Manual, Chapter 5, section 5100 and Appendix A, and according to 42 CFR 482 the Conditions of Participation for Hospitals. The purpose and process of the complaint survey were explained and an opportunity for questions was provided. Preliminary survey findings were presented at an exit conference on the afternoon of 1/04/19 with the hospital representatives. The representatives were thanked for their time and cooperation during the survey process. The representatives were afforded an opportunity to have their questions answered and given an opportunity to provide evidence of compliance with those requirements of which non-compliance had been found. None was provided. This report was electronically sent to the facility.	A 000	R/R 3/06/19 RJ	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

John Young

CEO, UT Southwestern University Hospitals

(X6) DATE 3/5/19

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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A 000	Continued From page 1 Complaint TX00303298 was substantiated with a deficiency cited.	A 000		
A 509	REPORTING ABUSES/LOSSES OF DRUGS CFR(s): 482.25(b)(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to report abuses and losses of controlled substances in accordance with applicable Federal and State laws, in that, Known, unaccounted for (Pulled from Pyxis, not documented as given or wasted) controlled substances were not reported to the DEA/BOP (Drug Enforcement Administration/Board of Pharmacy) in a timely manner upon their (hospital's) discovery during: Three (3) respective (Personnel #6, #7, and #8) investigations; and the Most current - Diversion Investigation Report findings (September to November 2018). Findings included (intravenous-IV; milligrams-mg; microgram-mcg; milliliters-ml; patient controlled analgesia-PCA) ~ 2016 event report (Personnel #6) reflected...suspected theft...Medications (Controlled Substances) that were not	A 509	As required per UHMM 06SOP (D) Controlled Substance Report of Loss-Theft, Destruction Return to Suppliers Hospital Standing Operating Procedure, any theft or loss of a significant amount of a controlled substance, is reported by the Director of Pharmacy or Pharmacist-In-Charge to the Drug Enforcement Administration (DEA), the Texas State Board of Pharmacy (TSBP), the University of Texas Southwestern (UTSW) Police, and the UTSW University Hospitals Chief Executive Officer (CEO). All of the unaccounted and unreconciled medications, recognized as such, were reported at the time of discovery by the Director of Pharmacy per the hospital standing operating procedure. Those not previously recognized, but identified during an unannounced complaint survey, were reported to align with the DEA reporting requirements. All unaccounted controlled substances from the December 2016 event report in relation to Personnel #6, was reported to Executive Leadership on January 4, 2019, the DEA on January 5, 2019, and the TSBP on January 10, 2019, by the Director of Pharmacy.	

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A 509	Continued From page 2 documented as given (or wasted) in the MAR (Medication Administration Record) but withdrawn from the Pyxis (Unaccounted for) were...Dilaudid PCA 25 mg/ml syringe; Fentanyl 100 mcg; Dilaudid 1 mg; Benadryl 50 mg...Fentanyl 100 mcg, Dilaudid 1 mg; Zofran 4 mg..." ~ The September to December 2016 (Personnel #7) Unaccounted for Controlled Substance Report included: Hydrocodone liquid 20 ml; Fentanyl 75 mcg; Fentanyl 25 mcg; Fentanyl 25 mcg; Dilaudid 0.5 mg; Dilaudid 0.4 mg; Propofol 1000 mg; Versed (Midazolam) 1 mg/mil - 77 mil; Propofol 1000 mg; Dilaudid 0.5 mg." ~ The (Most current) September to November 2018 "Monthly Diversion Report Investigation" Unaccounted (Not given or wasted) for medications included: (listed in order the report reflected) 9/4/18 Fentanyl 150 mcg; 9/14/18 hydromorphone 0.5 micrograms; 9/14/18 hydromorphone 0.4 mcg; 9/20/18 Tylenol #3, 1 tablet; 9/28/18 Fentanyl 25 mcg; 9/25/18 Hydrocodone 10-325 mg, 1 tab; 10/25/18 Dronabinol 5 mg, 1 capsule; 10/18/18 Diazepam 2 mg; 10/22/18 Fentanyl 25 mcg; 10/09/18 Fentanyl 50 mcg; 10/03/18 Tramadol 25 mg; October 2018 Hydromorphone 0.25 mg; Tramadol 50 mg; Morphine 2 mg; 11/30/18 Midazolam (Versed) 5 mg; 11/21/18 Midazolam 5 mg; and 11/03/18 Midazolam 5 mg. There were no submitted reports to Drug Enforcement Administration (DEA) or Board of Pharmacy (BOP) for the above known, unaccounted for medications. During a telephone interview on 1/04/19 ending at 5:30 PM, Personnel #5 was asked if the	A 509	The December 2016 event report stated Personnel #6 might have pilfered Dilaudid PCA 25 mg/ml syringe. Review of the Care Fusion Pyxis report reflected documentation that this medication was administered. Therefore, no discrepancy could be substantiated and thus, was not reported to regulatory bodies. All unaccounted controlled substances from December 2016 related to Personnel #7 were reported to Executive Leadership on January 4, 2019, the DEA on January 5, 2019, and the TSBP on January 10, 2019, by the Director of Pharmacy. However, since the 77mg/77mL Versed (Midazolam) was based on a 1mg/ mL bag, the product available to report on the DEA form 106 was 5mg/ml, which resulted in a total report of 75mg of midazolam. All unaccounted and/or unreconciled medications on the Diversion Investigation Report (September 2018 to November 2018) and medications noted on this report were reported to Executive Leadership on January 4, 2019, the DEA on January 5, 2019, and the TSBP on January 10, 2019, by the Director of Pharmacy Services.	

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A 509	Continued From page 3 DEA/BOP reporting was completed for the above findings. Personnel #5 stated, "No." The 5/31/18 "Drug Analysis Test Report" (Personnel #8) reflected, "...one IV Bag (Fentanyl bag) containing clear liquid...No controlled substance was identified..." During an interview on 1/04/19 from 9:15 AM to 10:48 AM, Personnel #5 showed pictures that were of the Fentanyl labeled IV bag that was tested. Personnel #5 was asked since the Fentanyl Bag did not contain Fentanyl, then there was unaccounted for medication. Personnel #5 stated, "Yes." Personnel #5 was asked if it was reported to the DEA/BOP. Personnel #5 stated, "No." The hospital's 09/17/18 "Report of Loss-Theft, Destruction, Return to Suppliers" Procedure required, "recorded amounts are to be reconciled and documented in a timely manner...Any theft or loss of a significant amount of a controlled substance, will be reported by the Director of Pharmacy...to the Drug Enforcement Administration (DEA #106 form Electronically), The Texas State Board of Pharmacy/BOP...Forward a copy of the form to BOP..." https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html (21 C.F.R. § 1301.76(b)) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and	A 509	During the onsite survey on January 4, 2019, autopsy findings from the Southwestern Institute of Forensic Science at Dallas were reviewed again. As the findings of "no controlled substance was identified" was incongruent with other findings in the case, the Medical Examiner was queried for explicit quantitative findings of blood obtained during autopsy. These findings revealed the presence of controlled substance, but were "below the threshold" of reportable findings. Only following this review process was there an awareness of the remaining Fentanyl infusion representing unaccounted for medication. Once this was recognized, this discrepancy was reported to the CEO on January 4, 2019, the DEA on January 5, 2019, and the TSBP on January 10, 2019, by the Director of Pharmacy. Sustainability: To establish further oversight and ensure sustainability, multiple processes have been streamlined and enhanced. These include, but are not limited, to the following: - reinforcement of the process of shift to shift reconciliation of controlled substances (Continued on next page)	

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A 509	Continued From page 4 submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors: (1) The actual quantity of controlled substances lost in relation to the type of business; (2) The specific controlled substances lost; (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances; (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known, (5) Whether the specific controlled substances are likely candidates for diversion; (6) Local trends and other indicators of the diversion potential of the missing controlled substance.	A 509	Sustainability: (Continued) - tracking of controlled substance access keys - refinement with continued monitoring of the Pyxis Controlled Substance Discrepancy Report These efforts will mitigate potential losses, improve timely identification, and aid in aligning practices with UHMM 06 Controlled Substance Hospital Policy. Additional education was provided to all frontline nursing leaders on February 19, 2019. This added education was designed to increase awareness and understanding of the reports, and the resources available to identify discrepancies. All frontline nurses will receive revised, detailed education on detection, reporting requirements, and expectations relative to the administration and handling of controlled substances by March 30, 2019. An algorithm was developed and implemented on January 22, 2019, to standardize and eliminate variation in reporting to both internal leadership and external regulatory bodies. The Controlled Substance and Diversion Committee (CSDC) is actively working with Pyxis and EPIC to develop a bidirectional interface to facilitate accuracy and timeliness of discrepancies between medications withdrawn from Pyxis relative to documentation of medications administered and/or wasted. In the interim, the CSDC continues to refine existing reports to facilitate identification of discrepancies. Findings of the CSDC will be reported to University Hospitals Safety Committee, the Medical Executive Committee and the University Hospitals Board.	